FSMA-Proposed Rules Foreign Supplier Verification Programs

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(Brian Pendleton): Thank you and good afternoon everyone. I'm very pleased to have the opportunity to talk with you today about FDA's proposed regulations on Foreign Supplier Verification Programs or FSVPs. FSVP is one of the core components of Title 3 of FSMA, the Food Safety Modernization Act, which adopts a risk-based preventive approach to improving the safety of food that's imported into the United States.

Here's some of the key principles that we have tried to incorporate into the proposed regulations on FSVP, the first being that importers would be responsible for ensuring that the food they bring into the US meets food safety standards.

This is not an entirely new concept either for industry or for FDA as I'll mention in a minute, importers of the juice and seafood are subject to certain verification requirements under existing regulations but for the first time requirements for food importers would be extended across nearly all foods. So, in FSMA's FSVP provisions, Congress acknowledged that importers have an important role to play in ensuring the safety of imported food.

A second key principle is that we have tried to make the proposed requirements flexible and risk-based, taking into account different types of hazards in foods as well as different types of suppliers.

And a third key principle is that as with all provisions in FSMA, we have tried to develop our FSVP regulations in a manner that's consistent with the agreement establishing the World Trade Organization as well as other treaties and international agreements to which United States is a party.

Ok so I do not have to look up, the screens right in front of me. Hey, how about that? That makes a lot of sense. Thank you. So who's covered under the proposal? Basically, nearly all importers unless in certain cases we have established certain exemptions, so nearly all importers would be required to establish and follow an FSVP. And under the proposed rule defines the US importer as the person who has purchased the food that is offered for import.

If there is no US owner of the food at the time of entry, the importer is the US consignee. If there's neither a US owner or a consignee at the time of entry, the importer is the US agent or a representative of the foreign owner or consignee. This definition of importer is consistent with FSMA, the statute. Note that the importer for FSVP purposes is not necessarily the importer of record, which could be a broker or a filer.

The definition is appropriate because the US owner or consignee has a direct financial interest in a food and is most likely to have knowledge and control over the supply chain. Another key definition that I want to mention is that of foreign supplier.

The proposed rule defines foreign supplier as an establishment that manufacturers or processes the food, raises the animal or harvests the food that's exported to the United States without further significant manufacturing or processing.

This would not include an establishment that only adds labeling or conducts a similar minimal activity. This definition of foreign supplier means that importers would not have to conduct verification of suppliers further upstream.

As I mentioned, there are certain exemptions from the FSVP proposal. The first is for importers of juice and seafood whose suppliers are in compliance with the HACCP regulations in Part 120 or 123. As I mentioned, these importers are already subject to verification requirements under the regulations. Also exempt would be food that's imported for research and evaluation purposes as well as food that's imported for personal consumption.

A partial exemption, which relates to importers of low-acid canned foods for microbiological hazards in LACF, importers would not be subject to the standard FSVP requirements. Instead, they would need to verify and document that the food was produced in accordance with the low-acid canned food regulations in Part 113 of the regulations. For other hazards in LACF, the importer would need to meet the FSVP requirements.

Other exemptions are for alcoholic beverages, food that's transshipped through the United States, as well as food that's imported for future export and isn't consumed or distributed in the United States.

Importers FSVPs, the plans that they have would have to do two things. First is that ensure that the foreign supplier that they're using uses processes and procedures that provide approximately the same level of public health protection as those that are required under the preventive controls or produce safety regulations that the agency also is developing at this time if they would apply to that particular foreign supplier.

The second aspect of what the FSVPs must do is that they need to ensure that food that's being imported isn't adulterated and isn't misbranded with respect to allergen labeling. In developing the proposed FSVP requirements, there are a number of factors that come into play into our proposal. The first concern is the type of the food product.

For example, we have certain provisions for processed food, for produce, as well as dietary supplements. The category of importer is also an important factor. For example, we have - I'll be talking about provisions for very small importers.

Another factor is the nature of the hazard that's been identified in the food. We have certain requirements that relate to very serious hazards. And a final issue is who in the supply chain will be controlling the hazard, whether that's the foreign supplier, the foreign suppliers, raw material or ingredient supplier, the importer, or even the importer’s customer.

Here is a list of the principal requirements that will apply to importers under the FSVP regulations. They would need to conduct a compliance status review of the foods that they want to import and the suppliers that they want to use. They would need to analyze the hazards in the foods that they import.

They would need to conduct certain supplier verification activities. They would need to review complaints, conduct investigations under certain circumstances, and take corrective actions when necessary and they would need to periodically reassess their FSVP.

They would need to ensure that they are identified as the importer of the particular food when the food is offered for entry into the United States and they would need to keep certain records. I'll talk about these in more detail in a moment but before I do, I should note that for nearly all of these activities, the importer would need to use a qualified individual, which we define in the proposal as a person who has the necessary education, training, and experience.

This could be -- but is not required to be -- an employee of the importer. Also, a qualified individual could be -- but again is not required to be -- a third party auditor that has been accredited in accordance with the accreditation system that the FDA is developing at this time and I think which Sharon Mayl will discuss in a few moments.

Also, a qualified individual could be an employee of a foreign food safety authority. For example, an official who has conducted an audit or inspection of a foreign supplier, in some cases an importer might be able to rely on such an audit or inspection. Compliance status review involves basically ensuring that the importer has knowledge of the particular food that they want to import and the foreign supplier that they want to use.

The proposal specifically requires that the importer would need to ensure or determine whether there are any FDA warning letters, import alerts, or requirements for certification that we have established for a particular food under our new authority under Section 303 of FSMA. Importers might also need to consider in conducting a compliance status review whether there are - whether it’s appropriate to look at FDA inspection reports, recall notices, as well as documents related to FDA seizures and injunctions.

A second key requirement of the FSVP proposal is to conduct a hazard analysis. The importer would need to identify what hazards are reasonably likely to occur in a food that they import. They can conduct their own hazard analysis or they can obtain and evaluate a hazard analysis that's been conducted by the foreign supplier that they are using for that food.

Of course, a core component of the FSVP regulation is to conduct supplier verification activities and I'll talk about those in more detail in a moment. Importers would need to review complaints that they receive concerning the foods that they import.

They would need to investigate the causes of adulteration or misbranding with respect to allergen labeling, and they would need to take appropriate corrective actions if for example the foreign supplier is not in compliance with applicable requirements and they would need to revise their FSVPs when they appear to be inadequate.

Another requirement is to periodically reassess the effectiveness of their FSVP. They would need to do this every three years or sooner if they become aware of new information about a potential hazard associated with a food. For example, information about the change to the source of a raw material that's used in a food they import or changes to the product formulation itself.

Another requirement is to ensure that they, the importer, are identified as the importer at the entry of the food into the United States. They would need to ensure that their name and their Dun and Bradstreet data universal numbering system number or DUNS number are provided at entry, and importers would need to keep certain records of these activities that I

discussed. FDA would need to - this is to ensure that FDA has a means of verifying that importers are actually meeting the FSVP requirements.

In general, records would need to be kept for two years after they are created or obtained. Records for procedures that relate to, for example, determining what an appropriate supplier verification activity would be would need to be kept for as long as those procedures are in place and for at least two years after they are no longer used.

A key factor in the proposed requirements for supplier verification activities is who will be responsible for controlling the hazards that have been identified as reasonably likely to occur in a particular food. This could be the importer's customer, the foreign supplier, the foreign supplier's raw materials or ingredient supplier, or the importer's customer in some cases.

And FDA in the proposal has suggested two options for when the foreign supplier controls the hazard in a food itself at their processing facility in the foreign country or the foreign supplier verifies that a hazard has been controlled by its raw material or ingredient supplier. And these two options differ primarily according to the nature of the hazard in the food.

Under option one of our proposal, if the foreign supplier is controlling the hazard at it's establishment and there's a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals or so-called SAHCODHA hazard, the importer would be required to conduct or obtain documentation of onsite auditing of the foreign supplier both before initially importing the food as well as at least annually thereafter.

We included this provision in option one because due to the nature of the harm that could result from such serious hazards, we feel that it might be appropriate to require the use of auditing, which is why they regard as one of the most effective verification tools. Auditing allows for observing physical conditions in a facility, interviewing employees, reviewing records, and verifying information in a way that might not be possible with other verification methods.

For non- SAHCODHA, these non-serious hazards that will be controlled by the foreign supplier as well as for all hazards that the foreign supplier verifies are being controlled by the raw material or ingredient supplier, the importer would need to conduct one or more of these four listed activities, that is onsite auditing, which I just mentioned, periodic or lot-by-lot sampling and testing, reviewing the foreign supplier's food safety records, or some other procedure that the importer has established as being effective in ensuring that a hazard is being controlled.

Option one, the onsite auditing requirement that's part of Option 1 also would apply to microbiological hazards in certain raw agricultural commodities that are fruits or vegetables.

Under Option 2 of the proposal, for all hazards that the foreign supplier either controls itself or verifies are being controlled by their raw material or ingredients supplier, importers would need to choose from among the verification activities that I just discussed, onsite auditing, sampling and testing, reviewing food safety records of the supplier or some other demonstrated appropriate procedure.

And in determining which of these four activities are appropriate to conduct and how often they should be conducted, the importer would need

to consider the risk that's presented by the hazard in the food, the probability that exposure to the hazard would result in serious harm, and the food and foreign supplier's compliance status.

So the key difference between Option 1 and Option 2 of the proposal is that while importers must consider the seriousness of the hazard in determining an appropriate supplier verification activity under Option 2, the third item here on this slide, onsite auditing, would not be mandatory under any particular circumstances under Option 2 whereas auditing would be mandatory in some cases under Option 1.

The FSVP proposal includes certain modified requirements for certain types of importers and certain types of imported food the first of which concerns dietary supplements. Unlike with the preventive controls proposal that we issued earlier this year, dietary supplements aren't exempt from the scope of the FSVP regulations.

But we have tried to tailor the regulations to these particular products. Importers of dietary supplements and dietary supplement components that will be subject to further processing in the United States and which will have to meet certain dietary supplement current good manufacturing practice regulations concerning specifications, for example, for components, for labeling, or for packaging, these would not be subject to most of the standard FSVP requirements that I've already discussed.

That's because meeting the dietary supplement specification requirements, along with complying with the other aspects of the dietary supplement CGMPs would provide adequate assurance, we feel, for the safety of the food.

It's a different approach with respect to finished dietary supplements that are imported. Importers of finished dietary supplements would be subject to most of the standard FSVP requirements. However, they would not be required to conduct hazard analysis for these products because this is not an approach that's used in the dietary supplement CGMP regulations.

And importers of finished dietary supplements would not be subject to any mandatory onsite auditing requirements that we might include in the final regulations for FSVP.

The second area of modified requirements that I want to talk about concerns very small importers and food from very small foreign suppliers. The proposed rule contains modified provisions for these very small entities reflecting the reduced risk that's associated with the lower volume of food from these importers and foreign suppliers.

The proposal defines a very small importer and a very small foreign supplier as having annual food sales of no more than $500,000. Eligibility would need to be documented annually. And importers under these provisions would not need to conduct hazard analysis.

And the supplier verification activity that they would need to be conduct would be to obtain written assurance every two years that their foreign supplier is producing food consistent with the US standards.

The last set of modified requirements that are included in the proposal concerns food from countries that have a food safety system that FDA has officially recognized as comparable or determined to be equivalent of that of the United States.

These modified requirements incorporate our systems recognition initiative under which we are conducting comprehensive reviews of the food safety systems of foreign countries to determine if they provide a similar, not the same exact, but a similar level of public health protection as under the US system. And under these proposed provisions in the FSVP proposal, food from suppliers in a country with a comparable food safety system would not be subject to most of the FSVP requirements if three conditions were met.

The supplier would need to be under the regulatory oversight of a comparable food safety system. The food itself would need to be within the scope of any agreement or arrangement concerning comparability or equivalence that was reached. And the foreign supplier would need to be in good compliance standing with the comparable or equivalent food safety authority.

And this could be as recognized in a list that the foreign food safety authority issues or any other form in which the food safety authority designates a supplier as being in good compliance standing. Under these modified provisions, well the only standard requirement that would apply would be that importers need to maintain a list of foreign suppliers.

Ensure that they are identified as the importer of the food at entry. And maintain records. However the importer would need to take corrective action if information indicated that hazards still were not being controlled.

As discussed both in the proposed rule for preventive controls and the FSVP proposed rule, the Agency intends to align the supplier verification provisions in the FSVP proposal with any supplier verification provisions that are included in the preventive controls final rule.

The preventive controls proposal itself doesn't include any codified language on supplier verification. But talks in some detail about the circumstances under which supplier verification activities would be appropriate. And requests comment on that. The current FSVP proposal itself states that it's an importer or its customer is controlling a hazard, verification would require documenting that the importer or its customer was in fact controlling the hazard.

However if the preventive control final rule includes supplier verification provisions, we think it would be appropriate to state in the FSVP final regulations that importers who also are food facilities that are in compliance with the supplier verification provisions in the PC would be deemed in compliance with the FSVP regulations. The goal here is to avoid imposing redundant requirements on entities that are both food importers and food facilities under the regulations.

Although the effective date of the FSVP final rule is expected to be 60 days after we publish the final rule, we intend to give importers additional time to come into compliance with the FSVP regulations. Generally this would be 18 months after we publish the final rule.

For importers whose suppliers would be subject to either the preventive controls or proto safety regulations, importers would be required to comply with FSVP six months after their foreign suppliers would be required to comply with the preventive controls or produce regulations.

So we're here today not only to provide information about some of our FSVP proposals but also to hear your feedback, your input, and your

concerns and questions that you might have about these proposed regulations. They are very important to us.

We have had two public meetings in the United States. We have met with officials in Europe, and China, and Mexico City, and Canada, among others. And we have learned so much about some areas where perhaps we need to provide additional detail, or discuss, or address that aren't included or addressed fully in proposal.

And we welcome your written comments on these proposed regulations. And I look forward to your questions and comments today. So we definitely encourage you to submit your comments on the proposal. And you can comment on the proposed rules at www.regulations.gov or www.fda.gov/fsma.

The proposed FSVP proposed rule was published in July of this year. And the comment period was recently extended to January 27 of next year. We also issued a combined preliminary regulatory impact analysis that includes both the foreign supplier verification proposal as well as the proposed regulations on the accreditation of third-party auditors.

And you can comment on this regulatory impact analysis. You can comment in the same fashion as you would comment on the proposed FSVP regulations themselves. And with that, I look forward to your questions and comments.

Sousan Altaie: I really seriously encourage you, and your government, and your industry that you're in contact with to go and give comments on these proposed rules. Because we can use help and it's better to implement the rule that

everybody has a stake in it. That's when you get a successful rule. So please let everybody know that you can go and comment on these rules.

Man: Can you tell us briefly please about how FDA considers the country's regulation system to be in compliance with FDA requirements? Or what is the steps or how can it happen for any country?

Brian Pendleton: I'm sorry, are you talking about the modified provision that I talked about comparability?

Man: Yes.

Brian Pendleton: Yes as I mentioned, we have a systems recognition initiative whereby we are looking at the totality of a foreign country's food safety system. So we are looking at their laws and regulations, their resources, their procedures that they use for how they can handle food borne outbreaks, their enforcement type procedures, all aspects of their food safety system and to make a determination as to whether we can view them as comparable to the US system.

It doesn't need to be exact but as comparable to them. And we have completed and reached a system recognition arrangement with New Zealand. That's the one country that we have -- the only country to this point -- that we have made such a determination.

We are in the process of working with other countries, evaluating their food safety systems under this systems recognition initiative. But at the moment that's the one country that we have officially reached an agreement on.

Man: Thank you.

Sousan Altaie: Brian, how does this systems recognition start? Is it by application put through?

Brian Pendleton: Yes there is a process for submission of a document by a foreign food safety authority that is interested in going through this process. And there is a, I forgot what the acronym. It's an ICAT but it's an information, I don't know Sharon, if you can...

Sharon Mayl: I don't know. But if you go on FDA's website you can find a lot of information about using the systems recognition and the whole process.

Sousan Altaie: So otherwise if you want to become a recognized food system, you have to submit an application. And it tells you on the webpage step-by-step how you go through the process and submit it to the FDA for their evaluation to determine comparability? So that's it.

Brian Pendleton: There's an initial submission of a self-assessment. So the foreign food safety authority would provide information about their operations, their laws, their regulations. And we would review that. And if appropriate then we would, the next step would be to conduct an audit of - the review of the country's food safety system.

So we would go to visit that country. And if the processes were successfully concluded, the current approach is to enter into an arrangement establishing, formally establishing the food safety systems as being comparable.